



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,553	01/31/2005	Ferenc Buzsaky	1103326-0786	1185

7470 7590 07/18/2008
WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

AHMED, HASAN SYED

ART UNIT	PAPER NUMBER
----------	--------------

1618

MAIL DATE	DELIVERY MODE
-----------	---------------

07/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,553	Applicant(s) BUZSAKY, FERENC	
	Examiner HASAN S. AHMED	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/15/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- Receipt is acknowledged of applicant's: (a) IDS, which was filed on 15 November 2007 and (b) amendment, which was filed on 27 March 2008.
- The 35 USC 102 rejection of the previous Office action is withdrawn in view of the amendment.

* * * * *

Election/Restrictions

Applicant argues that the restriction requirement is contrary to relevant regulations, citing 37 CFR 1.475.

Examiner respectfully submits that the processes of Groups V and VI are not "specially adapted for the manufacture of said product" (see 37 CFR 1.475(b)(1)) since claims 12 and 13 use open-ended "comprising" language; thus the process may include any number of elements not recited in the product claims.

Applicant is reminded that any nonelected processes of making and/or using an allowable product may be considered for rejoinder following the practice set forth in MPEP § 821.04(b) (See MPEP 1893.03(d)).

This application contains claims 1, 2, and 10-16 drawn to an invention nonelected with traverse in the reply filed on 27 March 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. (European Journal of Pharmaceutics and Biopharmaceutics, vol. 41, no 4, pages 219-228) in view of Hölzer et al. (WO 02/058677).

Petereit et al. disclose polymethacrylate and glycerol monostearate (GMS) formulations (see summary) comprising:

- the pharmaceutical core comprising a pharmaceutically active ingredient of instant claim 3(a) (see section 2.7);
- the film coat comprising an ethyl acrylate/methyl methacrylate copolymer of instant claim 3(b)(i) (see section 2.1);
- the film coat comprising the GMS of instant claim 3(b)(ii) (see section 2.3);
- the surface active agent of instant claim 3(b)(iii) (see section 2.4, tables 4-6);
- the nonionic surfactant (GMS) of instant claim 3 (see section 2.3); and
- the modified release formulation of instant claim 5 (see section 2.1).

Petereit et al. explain that combining the disclosed ingredients into one formulation is beneficial because the amount of glidant required is reduced, and suspensions are stabilized (see summary).

The Petereit et al. reference differs from the instant application in that it does not teach the sorbitan esters of instant claim 3, the plurality of beads of instant claim 4, the modified release composition with a core comprising the active ingredient for treatment of cardiovascular disease of instant claim 6, the beta-blocking adrenergic agent of instant claim 7, the metoprolol of instant claim 8, or the metoprolol salt of instant claim 9. However, these formulations are well known in the art, as shown by Hölzer et al.

Hölzer et al. teach a film coated pharmaceutical composition (see abstract) with a core comprising:

- the sorbitan ester of instant claims 3 and 4 (see page 11, line 2);
- the plurality of beads of instant claim 4 (see page 6, line 25);
- the active ingredient for treatment of cardiovascular disease of instant claim 6 (see page 7, line 22);
- the beta-blocking adrenergic agent of instant claim 7 (see page 7, line 23);
- the metoprolol of instant claim 8 (see page 7, line 29); and
- the metoprolol salt of instant claim 9 (see page 8, line 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the disclosed ingredients into one formulation, as taught by Petereit et al. in view of Hölzer et al. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because of advantages such as a reduction in the amount of glidant required, and stabilized suspensions, as explained by Petereit et al.

* * * * *

Response to Arguments

Applicant's arguments filed 27 March 2008 regarding 35 USC 103 have been fully considered but they are not persuasive.

Applicant argues that the Hölzer reference is not prior art. See remarks, page 8.

Examiner respectfully disagrees. Hölzer is an international application which was filed after 29 November 2000, was published in English, and designated the U.S. As such, the 35 USC 102(e) date for this reference is the international filing date, which is 22 January 2002.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1618